

REMARKS

Applicants have canceled claim 12 without prejudice. In addition, Applicants have amended claim 1 without prejudice as described below and have added new claim 18. Accordingly, claims 1-11, 13, 14, 16, 17, and new claim 18 are pending. Applicants reserve the right to pursue the subject matter of claims as originally pending in future applications.

The Claim Amendments

Applicants have amended claim 1 to recite a complex, wherein the complex comprises a nucleic acid molecule and a charged copolymer of the general formula I, wherein the charged copolymer is bound in the complex via ionic interactions. This amendment, which is supported throughout the specification, more particularly points out that the complex comprises a nucleic acid molecule and a charged copolymer and that the copolymer is bound in the complex via ionic interactions (see, e.g., lines 8-11 on page 14, lines 8-9 on page 17, and lines 28-32 on page 40). Applicants have also amended claims 1 and 4 to correct their form. In addition, Applicants have added new claim 18. Support for this claim is found, for example, at lines 5-10 on page 19. The claim amendments introduce no new matter.

The Rejections

Applicants thank the Examiner for withdrawing the rejections under 35 U.S.C. § 112. Applicants address the Examiner's rejections under 35 U.S.C. § 102 and § 103 below.

35 U.S.C. § 102(b): Novelty

The Examiner has maintained the rejection of claims 1-9, 12-14, 16, and 17 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 98/19710 ("Schacht"). Applicants traverse.

In order to anticipate the amended claims, Schacht must teach or inherently embody all of the elements of the claims. Schacht does not. Therefore, the amended claims are patentable over Schacht.

In the December 17, 2004 Office Action, the Examiner contended that Schacht taught a combination of a carrier complex comprising a therapeutic nucleic acid molecule and a charged copolymer that met the structural limitations of the then pending claims. In the June 17, 2005 Response, Applicants demonstrated that Schacht did not teach various elements of the pending claims and therefore failed to anticipate the claimed invention. Specifically, Applicants pointed out that the pending claims recited components: (1) a carrier, (2) a nucleic acid molecule, and (3) a charged copolymer, whereas Schacht only recited complexes comprising (1) a nucleic acid molecule, (2) a charged copolymer and (3) a hydrophilic polymer. Thus, Schacht did not recite the additional feature of a carrier. Applicants further explained that although Schacht used the term “carrier”, it was used in the context of the nucleic acid-containing complexes as a whole. By contrast, in the pending claims the term referred to a particular component of the claimed combination.

In the present Office Action, the Examiner has acknowledged that Schacht refers to the entire nucleic-acid-containing complex as a “carrier” (Office Action page 4). However, the Examiner argues that based on the definition of “carrier” on page 18 of the instant specification and dependent claim 12, which recites a carrier obtainable by cross-linkage of a co-polymer of claim 1, Applicants “envision the carrier as being a part of the complex itself” (Office Action page 4). Therefore, according to the Examiner, the fact that Schacht “teaches that the complex comprises the carrier (e.g., HPMA) as part or the particle itself, does not exclude the reference as art” (Office Action pages 4-5). The Examiner further contends that Schacht indicates that the particles can be comprised in a pharmaceutical composition and indicates that the complex can be in an aqueous solution. The Examiner contends that these “examples” thus recite compositions that are “carriers” as defined in the instant specification.

Applicants disagree with the Examiner’s characterization of Schacht and its alleged applicability to the previously pending claims. Nevertheless, Applicants have amended claim 1 to more particularly point out the claimed subject matter and make clear that the carrier and nucleic acid-containing complex are distinct components of the claimed combination. This amendment makes clear that the carrier is a component of the claimed combination and that the complex itself comprises the nucleic acid molecule and a charged copolymer of the general formula I.

In addition, Applicants' amendment to claim 1 more particularly points out the claimed subject matter by reciting that the copolymer is bound in the complex via ionic interactions. Accordingly, even if m and n in the structure of claim 1 are zero, the cationic polymers of Schacht do not anticipate or render obvious the claimed invention.

In the December 17, 2004 Office Action, the Examiner referred to Figures 4 and 11 of Schacht to argue that Schacht allegedly recites copolymers of the general formula I as claimed in the instant application. The structure of Figure 11 in Schacht depicts the amphiphilic polymer as appended to the polymer backbone rather than as part of the backbone itself, as claimed in the present invention. Accordingly, the structure in Figure 11 does not recite a polymer of the general formula I. In addition, Figure 4 of Schacht does not anticipate the claimed invention as amended claim 1 more particularly points out that the charged copolymer of general formula I is bound in the complex via ionic interactions. Figure 4 depicts a hydrophilic polymer that is used in Schacht to bind (via covalent interactions) a cationic polymer, which in turn self assembles with DNA (see Example 11 of Schacht). Accordingly, the polymer of Figure 4 is bound in the complex via covalent interactions. Schacht, therefore, does not depict a polymer as recited in claim 1 of the instant application. Schacht thus fails to anticipate the claimed invention.

Accordingly, because Schacht neither explicitly nor implicitly teaches each and every limitation of the amended claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. § 103(a): Obviousness

The Examiner has maintained the rejection of claims 1 and 9-11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Schacht in view of United States patent 5,863,984 ("Doillon"). The Examiner contends that Schacht teaches carriers while Doillon teaches that a PEG-modified collagen sponge can be used as a drug delivery vehicle. Applicants traverse.

To establish a *prima facie* case of obviousness, the following three criteria must be met: (i) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (ii) there must be a reasonable expectation of success of combining the cited

references to arrive at the claimed invention, and (iii) the prior art references must teach or suggest each and every limitation of the claimed invention. MPEP 2142-2143.

As demonstrated above, Schacht fails to recite complexes as claimed in the instant application. Accordingly, Schacht, even in further view of the collagen sponge recited in Doillon, fails to teach or suggest each and every limitation of the claimed invention. Thus the combination of Schacht with Doillon fails to render obvious the claimed invention. Applicants request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In view of at least the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance and respectfully request favorable reconsideration. Applicants believe no additional claim fees are due. The Director has already been authorized to charge any fees required, in addition to the fees supplied with the Request for Continued Examination and the Request for Extension of Time, to Deposit Account No. 06-1075 under Order No. 003747-0061.

Respectfully submitted,

By


James F. Haley, Jr.

Reg. No. 27,794

Attorney for Applicants

FISH & NEAVE IP GROUP

ROPES & GRAY LLP

Customer No. 1473

1251 Avenue of the Americas

New York, New York 10020-1105

Tel.: (212) 596-9000

Fax: (212) 596-9090